國立臺灣大學 104 學年度碩士班招生考試試題

1. Drug-A is mainly metabolized by the liver and is a substrate of CYP2C19. The pharmacokinetic properties of drug-A are described below:
   F (oral) = 24%
   fu = 13%
   elimination half-life t1/2 = 3.9 hours
   Vd = 4.3 L/kg
   a. Based on suitable equations, what would be the change in hepatic clearance of drug-A in patients who are CYP2C19 poor metabolizers when it is given by oral administration. **(10 points)**
   b. Based on suitable equations, explain how a change in (1) hepatic blood flow or (2) plasma protein binding would affect hepatic clearance of drug-A when it is given by intravenous administration. **(10 points)**

2. For bioequivalence studies, why are C_{max} and AUC acceptable to evaluate that two drug products are bioequivalent. **(10 points)**.

3. A drug has the following pharmacokinetic properties:
   fu = 0.2
   fe = 0.6
   elimination half-life t1/2 = 0.231 hours
   This drug was given to a male patient (80 kg) by intravenous infusion at a rate of 240 mg/hr. At 7 hours after infusion, the plasma drug concentration was 10 μg/ml.
   (a) What is the apparent volume of distribution for this drug? **(5 points)**
   (b) What is the probable mechanism for renal clearance of this drug? **(10 points)**

4. Describe the applications of BCS (Biopharmaceutics Classification System) and BDDCS (Biopharmaceutics Drug Disposition Classification System). **(10 points)**

5. P-glycoprotein (MDR1; ABCB1) is an efflux transporter expressed at the intestine, liver, kidney, brain, and many others. Describe the roles of P-glycoprotein in ADME of its substrates. **(20 points)**

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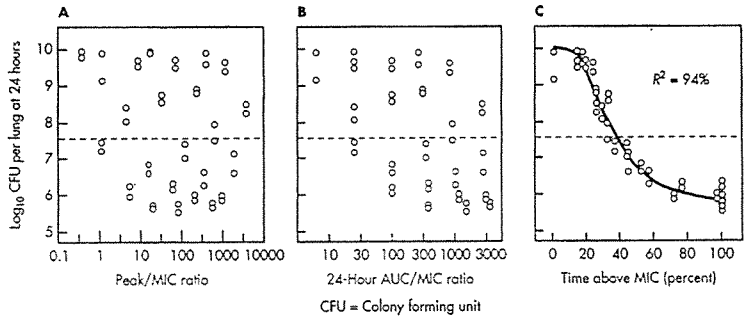
6. Describe and explain the pharmacokinetic properties for drugs that are sensitive to be considered for a bridging study. **(20 points)**

7. The followings describe the relationship among three pharmacodynamic parameters and the number of *Klebsiella pneumoniae* (indicated by CFU) in the lungs of neurotroponic mice after 24-hr therapy with cefotaxime.
Describe how these findings are related to the PK/PD properties of cefotaxime.
(5 points)



Relationship between three pharmacodynamic parameters and the number of *Klebsiella pneumonia* in the lungs of neurotroponic mice after 24-hr therapy with cefotaxime. Each point represents one mouse.

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